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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,810	03/01/2002	Isabelle Arnould	1721-39	8335

7590

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EXAMINER

WHISENANT, ETHAN C

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 04/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/980,810

Applicant(s)

ARNOULD ET AL.

Examiner

Ethan Whisenant, Ph.D.

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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## DETAILED ACTION

1. The applicant's Preliminary Amendment filed 06 DEC 02 has been entered. Following the entry of the Preliminary Amendment, **Claim(s) 1-6** is/are pending.

### ABSTRACT OF THE DISCLOSURE

2. The abstract of the disclosure is objected to because it fails to meet the standards of 37 CFR 1.72. Correction is required. The abstract of the technical disclosure in the specification must commence on a separate sheet, preferably following the claims, under the heading "Abstract" or "Abstract of the Disclosure." The abstract in an application filed under 35 U.S.C. 111 may not exceed 150 words in length. The purpose of the abstract is to enable the United States Patent and Trademark Office and the public generally to determine quickly from a cursory inspection the nature and gist of the technical disclosure. The abstract will not be used for interpreting the scope of the claims See MPEP § 608.01(b). 608.01(b).

### 35 USC § 101

3. 35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title".

### Claim Rejections - 35 USC § 101

4. **Claim(s) 5** is/are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. Claim 8 is nonstatutory because "the use of" is not a patentable category under 35 U.S.C. § 101.

**35 USC § 112- 2ND PARAGRAPH**

- 5.** The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**CLAIM REJECTIONS under 35 USC § 112- 2ND PARAGRAPH**

- 6.** **Claim(s) 1-6** is/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

**Claim 1** is indefinite because of the use of the phrase "preferably followed by ....".

**Claim 4** is unclear because of the use of the phrase "i.e. the number of ..". The use of exemplary claim language makes these claims indefinite. See the MPEP at 2173.05(d). It is well established that the description of examples or preferences is properly set forth in the specification rather than the claims. If stated in the claims, examples and preferences lead to confusion over the intended scope of a claim. Ex parte Hall, 83 USPQ 38 (Bd. App. 1949).

**Claim 1** is indefinite because of the phrase "obtaining a transcription" on line 1 is nonsequitur.

**Claim 3** is indefinite because of the phrase "in addition" on line 2 is nonsequitur.

**Claim 4** is also indefinite because the phrase "reliably reflecting" on line 2 is a relative term that make the claim confusing.

**Claim 5** is indefinite because the phrase "high-density filters" on line 2 is a relative term that make the claim confusing.

**Claim 6** is indefinite because the phrase "the DNA" on line 4 lacks proper antecedent basis.

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**35 USC § 102**

**7.** The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that may form the basis for rejections set forth in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) The invention was described in --

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a)

**CLAIM REJECTIONS UNDER 35 USC § 102**

**8.** **Claim(s) 1-2,** is/are rejected under 35 U.S.C. 102(b) as being anticipated by Weissman et al. [4,738,928 (1988)].

Weissman et al. teach a method of obtaining a transcription (i.e. a transcript) as recited in Claims 1-2. See, for example, Column 4, beginning at about line 17.

**9.** **Claim(s) 1-2, 4-6** is/are rejected under 35 U.S.C. 102(a) as being anticipated by Decraene et al. (NOV 1999)].

Decraene et al. teach a method of obtaining a transcription (i.e. a transcript) as recited in Claims 1-2. In addition, Decraene et al. teach cDNA mixtures as recited in Claim 4 as well as their use in hybridization experiment to analyze gene expression.

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**35 USC § 103**

**10.** The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**11.** This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligations under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

**CLAIM REJECTIONS UNDER 35 USC § 102/103**

**12.** **Claim(s) 4** is/are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Weissman et al. [4,738,928 (1988)].

Weissman et al. teach a composition comprising all of the limitations of Claim 4 except these authors do not explicitly teach using their cDNA mixtures to determine the expression level of gene(s). However, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. *In re Casey*, 152 USPQ 235 (CCPA 1967); *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

**CLAIM REJECTIONS UNDER 35 USC § 103**

**13.** **Claim(s) 3** is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Weissman et al. [4,738,928 (1988)] as applied against Claim 1 above and further in view of the GeneAmp Reagent Kit / Instructions for Use (1988).

Weissman et al. teach a method requiring all of the elements recited in Claim 3 except these authors do not explicitly teach incorporating the reagent necessary to perform their method(s) into a kit. However, as evidenced by GeneAmp Reagent Kit / Instructions for Use, it was well known at the time of the invention to place the reagents needed to perform a nucleic acid based assay into a kit format. Therefore, absent an unexpected result, it would have been *prima facie* obvious to the ordinary artisan at the time of the invention to modify the teachings of Weissman et al. with the teachings of the GeneAmp Reagent Kit / Instructions for Use wherein the reagents necessary to perform the method(s) taught by of Weissman et al. are placed into a kit format. The ordinary artisan would have been motivated to make this modification in order to take advantage of the savings and efficiency afforded by kits when performing the method(s) taught by Weissman et al.

**14.** **Claim(s) 3** is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Decraene et al. (NOV 1999) as applied against Claim 1 above and further in view of the GeneAmp Reagent Kit Instructions for Use (1988).

Decraene et al. teach a method requiring all of the elements recited in Claim 3 except these authors do not explicitly teach incorporating the reagent necessary to perform their method(s) into a kit. However, as evidenced by GeneAmp Reagent Kit / Instructions for Use, it was well known at the time of the invention to place the reagents needed to perform a nucleic acid based assay into a kit format. Therefore, absent an unexpected result, it would have been *prima facie* obvious to the ordinary artisan at the time of the invention to modify the teachings of Decraene et al. with the teachings of the GeneAmp Reagent Kit / Instructions for Use wherein the reagents necessary to perform the method(s) taught by of Decraene et al. are placed into a kit format. The ordinary artisan would have been motivated to make this modification in order to take advantage of the savings and efficiency afforded by kits when performing the method(s) taught by Decraene et al.

**Conclusion**

**15.** Claim(s) 1-6 is/are rejected and/or objected to for the reason(s) set forth above.

**16.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (703) 308-6567. The examiner can normally be reached Monday-Friday from 8:30AM -5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

The fax number for this Examiner is (703) 746-8465. Before faxing any papers please inform the examiner to avoid lost papers. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989). Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist whose telephone number is (703) 308-0196.



Ethan Whisenant, Ph.D.  
Primary Examiner